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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,012	02/01/2006	Neil Lee Spector	PR60419USw	9491

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GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B482
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
08/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/567,012	SPECTOR ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/14/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6, 7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 1-3, 6, 7 and 9 are pending.

Claim 1 has been amended.

Claims 1-3, 6, 7 and 9 are examined on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The rejection of claims 1-3, 6, 7 and 9 under 35 U.S.C. 102(b) as being anticipated by Baselga et al. (Journal of Clinical Oncology 14(3): 737-744, March 1996) is maintained.

Applicants aver "Baselga… does not provide any discussion of how levels of ECD correlate with treatment choice, or how levels of serum ECD correlate with the action of GW572016.", see Remarks submitted May 14, 2008, page 3, last paragraph. Applicants reiterate teachings of the MPEP and conclude arguments noting the

Examiner did not explain what text of the claim is regarded as the "active step". These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' active step is "…determining whether the tumor expresses $p95^{ErbB2}$ ". The corollary statement, "where expression of $p95^{ErbB2}$ indicates said subject is more likely to exhibit a favorable clinical response to treatment…" is an immediate or natural consequence based upon meeting the active step. Baselga discloses means for determining and measuring HER-2/neu ECD levels in an individual's serum sample having metastatic breast carcinomas that overexpress HER2 as agreed upon by Applicants, see Remarks, page 3, last paragraph. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on the claimed method. Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. The MPEP 2111.02 notes "statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second step of claim 1, correlating $p95^{ErbB2}$ expression with potential response to therapy does not appear to be a manipulative step, hence the rejection is maintained.

4. The rejection of claims 1-3, 6 and 7 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number US 2003/0219842 A1 (filed February 27, 2003) is maintained.

Applicants' arguments are similar to those presented in the preceding 102(b) rejection, concurring with the prior art exemplifying determination of tumor expression of $p95^{ErbB2}$, reiterating teachings of the MPEP and arguments noting the Examiner did not explain what text of the claim is regarded as the "active step". These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' active step is "…determining whether the tumor expresses $p95^{ErbB2}$ ". The corollary statement, "where expression of $p95^{ErbB2}$ indicates said subject is more likely to exhibit a favorable clinical response to treatment…" is an immediate or natural consequence based upon meeting the active step. The publication discloses means for determining and measuring HER-2/neu ECD levels in an individual's serum sample having solid tumor cancers of the breast (mammary), ovary, colon, head and neck, bladder, liver and lung before, during and after anti-neoplastic treatment or therapy regimen using immunoassays, see page 3, section 0021; page 4, sections 0039 and 0041; page 5, sections 0050 and 0053; and page 12, section 0102. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on the claimed method. Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. The MPEP 2111.02 notes "statements in the preamble reciting the purpose or intended use of the claimed invention must be

evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second step of claim 1, correlating p95 ^{ErbB2} expression with potential response to therapy does not appear to be a manipulative step, hence the rejection is maintained.

5. The rejection of claims 1-3, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Harris et al. (Journal of Clinical Oncology 19(6): 1698-1706, March 15, 2001/ IDS reference 14, submitted February 1, 2006) is maintained.

Applicants' arguments are similar to those presented in the preceding 102(b) rejection, concurring with the prior art exemplifying determination of tumor expression of p95 ^{ErbB2}, reiterating teachings of the MPEP and arguments noting the Examiner did not explain what text of the claim is regarded as the "active step". These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' active step is "…determining whether the tumor expresses p95 ^{ErbB2} ". The corollary statement, "where expression of p95 ^{ErbB2} indicates said subject is more likely to exhibit a favorable clinical response to treatment…" is an immediate or natural consequence based upon meeting the active step. Harris discloses assessment of *HER-2* ECD in serum samples from breast cancer patients using an enzyme-linked immunoassay, see page 1699, 2nd column, Materials…section. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on the claimed method.

Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. The MPEP 2111.02 notes "statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second step of claim 1, correlating $p95^{ErbB2}$ expression with potential response to therapy does not appear to be a manipulative step, hence the rejection is maintained.

6. The rejection of claims 1, 2, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Molina et al. (Clinical Cancer Research 8: 347-353, February 2002/ IDS reference 3, submitted February 21, 2007) is maintained.

Applicants' arguments are similar to those presented in the preceding 102(b) rejection, concurring with the prior art exemplifying determination of tumor expression of $p95^{ErbB2}$, reiterating teachings of the MPEP and arguments noting the Examiner did not explain what text of the claim is regarded as the "active step". These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' active step is "…determining whether the tumor expresses $p95^{ErbB2}$ ". The corollary statement, "where expression of $p95^{ErbB2}$ indicates said subject is more likely to exhibit a favorable clinical response to treatment…" is an immediate or natural

consequence based upon meeting the active step. Molina discloses a method of p95 analysis in breast cancer tissues implementing western blot analysis, see page 348, 2nd column, Western…section; Table 1 on page 349. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on the claimed method. Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. The MPEP 2111.02 notes "statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second step of claim 1, correlating p95 ^{ErbB2} expression with potential response to therapy does not appear to be a manipulative step, hence the rejection is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The rejection of claims 1-3, 6, 7 and 9 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number US 2003/0219842 A1

(filed February 27, 2003), and further in view of Baselga et al. (Journal of Clinical Oncology 14(3): 737-744, March 1996) is maintained.

Applicants set forth their claimed invention and differences between their invention and the prior art, see Remarks, page 7, section 6. Applicants reiterate teachings of the MPEP, in particular Graham v. John Deere Co. analysis and conclude arguments noting "…*Graham* factual findings have not been established, and thus a prima facie case of obviousness has not been made". , see page 9 of the Remarks. These points of view have been carefully considered, but found unpersuasive.

Applicants are reminded the active step is "…determining whether the tumor expresses p95 ^{ErbB2} ". The corollary statement, "where expression of p95 ^{ErbB2} indicates said subject is more likely to exhibit a favorable clinical response to treatment…" is an immediate or natural consequence drawn upon based on meeting the active step. As stated earlier the publication discloses means for determining and measuring HER-2/neu ECD levels in an individual's serum sample having solid tumor cancers of the breast (mammary), ovary, colon, head and neck, bladder, liver and lung before, during and after anti-neoplastic treatment or therapy regimen using immunoassays, see page 3, section 0021; page 4, sections 0039 and 0041; page 5, sections 0050 and 0053; and page 12, section 0102. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on the claimed method. Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. Applicants' attention is directed to MPEP 2111.02 "statements in the preamble reciting the purpose

or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second step of claim 1, correlating $p95^{ErbB2}$ expression with potential response to therapy does not appear to be a manipulative step, hence the rejection is maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
30 July 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643